

### REMARKS

Favorable reconsideration of this application is respectfully requested in view of the previous amendments and following remarks.

Claims 1-18, 20, 21 and 26-33 are pending. By this Amendment claims 1-4, 10, 11, 14-18 and 20 are amended, claims 19 and 22-25 are canceled without prejudice or disclaimer and new claims 26-33 are added. No new matter has been added.

The Office Action rejects claims 1, 2, 5, 6, 9 and 10 under 35 U.S.C. §102(b) over U.S. Patent No. 5,180,504 to Johnson et al.; claims 11, 14-19 and 21-23 under 35 U.S.C. §102(b) or, in the alternative, under 35 U.S.C. §103(a) over Johnson; claims 3, 4, 7, 8 and 20 under 35 U.S.C. §103(a) over Johnson in view of U.S. Patent No. 6,733,433 to Fell; and claims 12, 13, 24 and 25 under 35 U.S.C. §103(a) over Johnson in view of U.S. Patent No. 5,496,302 to Minshall et al. These rejections are respectfully traversed.

Independent claims 1 and 2 define a method for assembling a blood treatment circuit by aseptically connecting to each other a connected bag set which has previously been sterilized and a filter unit which has previously been sterilized. The connected bag set includes a first tube and the filter unit includes a second tube. The claimed method set forth in claims 1 and 2 involves cutting the first tube so that the first tube comprises first and second cut ends, and cutting the second tube so that the second tube comprises first and second cut ends. The first cut end of the first tube is aseptically connected to the first cut end of the second tube, and the second cut end of the first tube is aseptically connected to the second cut end of the second tube. This claimed method is not disclosed or suggested by Johnson.

Johnson discloses a blood collection system including a primary bag or container 16 having one or more integrally attached transfer bags or containers 18 and 20. A filtration assembly 14 is initially not joined to the blood processing assembly 12. The filtration assembly 14 includes a transfer container 34. The filtration assembly 14 is attached to the primary bag 16 via a connection assembly 48 that permits selective attachment of the filtration assembly 14 to the blood collection assembly 12. As discussed in Johnson beginning at column 6, line 34, the connection assembly 48 can form a molten seal between the transfer tubing 30 of the primary bag 16 and the tubing end portion 54 of the filtration assembly 14. In an alternate arrangement, the connection assembly 48 includes two mating sterile connection devices. In another alternate arrangement, two mating sterile connection devices 66a and 66b are used. None of these three disclosed alternatives involves cutting first and second tubes (one of which has ends connected to a filter unit as claimed) to form a pair of cut ends on each tube, and then aseptically connecting each cut end of one tube to a respective cut end of the other tube. Thus, for at least these reasons, claims 1 and 2 are distinguishable over Johnson.

Claims 3 and 4 are similarly distinguishable over the disclosure in Johnson. In claims 3 and 4, the connected bag set includes a third tube, and the second tube and third tube are cut to form respective first and second cut ends. The first cut end of the third tube is aseptically connected to the first cut end of the second tube, and the second cut end of the third tube is aseptically connected to the second cut end of the second tube. For the reasons similar to those discussed above with respect to claims 1 and 2, claims 3 and 4 are distinguishable over Johnson as the cited reference fails to disclose cutting two tubes, one of which has ends connected to a

filter unit as claimed, to form a pair of cut ends on each tube, with each cut end of one tube being aseptically connected to a respective cut end of the other tube.

The Office Action cites Fell as disclosing a blood treatment system including a plurality of secondary bags. In Fell, the filter 54 is not connected to the tubes connecting bags 42, 43 and 44. Thus, Fell does not overcome the deficiencies of Johnson.

Amended independent claim 14 defines a filter unit comprising, in combination with the other claimed features, a filter unit to be aseptically connected to a connected bag set in order to assemble a blood treatment circuit, with the connected bag set including a first tube, and the filter unit comprising an inlet an outlet and a second tube whose ends are connected to the inlet and the outlet. The first tube is aseptically connected to the second tube by using an apparatus for aseptically connecting tubes that cuts the first and second tubes and then aseptically connects one of the first and second tubes to the other at their cut surfaces. One of the cut surfaces of the first tube facing one direction is connected to one of the cut surfaces of the second tube facing an opposite direction. The other of the cut surfaces of the first tube facing the opposite direction is connected to the other of the cut surfaces of the second tube facing the one direction. This places the filter along the first tube.

Johnson discloses at Fig. 4 that the filtration assembly 14 is joined to the blood processing assembly 12 at the connection assembly 48. The tubing of the blood collection assembly and of the filtration assembly is not cut to result in two cut ends, with each cut end of one tube being aseptically connected to one of the cut ends of the other tube. Thus, Johnson does not disclose or suggest a filter unit as recited in claim 14.

Similarly, in claim 20 the connected bag set includes a third tube to connect secondary bags to one another. One of the cut surfaces of the third tube facing one direction is connected to one of the cut surfaces of the second tube facing an opposite direction and the other of the cut surfaces of the third tube facing the opposite direction is connected to the other of the cut surfaces of the second tube facing the one direction. As pointed out above, Johnson lacks disclosure of the tubing of the blood collection assembly 12 and of the filtration assembly 14 being cut to result in two cut ends, with each cut end of one tube being aseptically connected to one of the cut ends of the other tube. In addition, Fell does not overcome the deficiencies of Johnson. In Fell, the filter 54 is not connected to the tubing between the bags 42, 43 and 44.

New independent claim 31 defines a filter unit comprising a filter possessing an inlet and an outlet, and a tube comprising a first end connected to the inlet of the filter and a second end connected to the outlet of the filter so that the tube extends between the inlet and outlet of the filter. As recited in Claim 31, the tube is not connected to a container between the first and second ends of the tube, and the filter unit is sterilized. The filter unit is adapted to be put to use by cutting the tube between the first and second ends to result in cut ends of the tube and aseptically connecting the ends of the tube to another tube.

The filtration assembly 14 disclosed in Johnson is specifically configured to include the transfer container 34. This transfer container 34 is connected to the tube that extends between the inlet and outlet of the filtration device 40. Thus, new claim 31 is patentably distinguishable over the disclosure in Johnson in that Johnson lacks disclosure of a tube comprising first and second ends connected to the inlet and

outlet of the filtration assembly, and wherein the tube is not connected to a container between the first and second ends of the tube. Further, considering Johnson's disclosure in its entirety, it would not have been obvious to do away with the container 34 because the inclusion of the container 34 in the filtration assembly 14 is necessary to Johnson's disclosed manner of use.

Johnson does not specifically describe how the filtration assembly 14 is manufactured. To the extent it is thought that the container 34 might be connected to the tube after the tube is connected to the filtration device 40 (i.e., there might be a point in time when, prior to connection of the container 34, there is no container connected to the tube of the filtration device 40), it is noted that claim 31 recites the filter unit being sterilized. In Johnson, any sterilization of the filtration assembly 14 would presumably take place after the container 34 is connected to the tube extending between the inlet and outlet of the filtration device 40.

Minshall does not overcome the deficiencies of Johnson and Fell noted above.

The remaining dependent claims are allowable at least by virtue of their dependence from allowable independent claims. Thus, a detailed discussion of the additional distinguishing features recited in each of the dependent claims is not set forth at this time. However, several points about the dependent claims are noted.

Claim 11 recites that the marks on the first and second tubes which indicate that the first and second tubes have been correctly connected to each other are comprised of an expanded outside diameter of the tubes. Claim 18 includes a similar recitation with respect to the second tube. This is not disclosed in Johnson.

Further, contrary to the observation in the Official Action, this is not a product-by-process recitation.

New claim 32 recites the two spaced apart marks on the tube at positions on either side of a location where the tube is to be cut, wherein the two marks are distinguishable from one another. New claim 33 set defines that a portion of the tube has an expanded outside diameter relative to parts of the tube on both sides of the portion of expanded diameter to indicate correct connection of the tube to the another tube. These claims further distinguish over Johnson.

In view the foregoing remarks, the Examiner is respectfully urged to reconsider and withdraw the outstanding rejections.

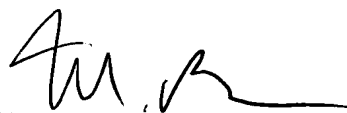
In the event that there are any questions concerning this response, or the application in general, the Examiner is respectfully urged to telephone the undersigned attorney so that the prosecution of the application may be expedited.

Respectfully submitted,

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